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November 9, 1999

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FILE: INRP:041

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**BOX AF**

Assistant Commissioner for Patents  
Washington, DC 20231

RE: SN 08/758,033 "METHODS AND COMPOSITIONS FOR THE TREATMENT OF  
CANCER" - Gary L. Clayman (UTMDACC:526)

Sir:

Enclosed for filing in the above-referenced patent application is the following:

- (1) An Appeal Brief (in triplicate), with accompanying appendices 1 and 2, and exhibits A-P;
- (2) A Petition to Direct Entry of Amendment Under 37 C.F.R. § 1.127 and 1.181;
- (3) An Amendment Under 37 C.F.R. § 1.116;
- (4) A Declaration Under 37 C.F.R. § 1.131 of Dr. Gary Clayman;
- (5) A check in the amount of \$300.00 as the fee for the appeal brief; and
- (6) A return receipt postcard. Please date-stamp the enclosed postcard and return it to us for our files.

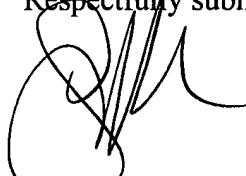
A fee as set forth in 37 C.F.R. §§ 1.16-1.21 in the amount of \$300.00 is enclosed herewith. If an appropriate check has not been enclosed, or if it is insufficient under 37 C.F.R §§ 1.16 to 1.21, the

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Assistant Commissioner for Patents  
November 9, 1999  
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Commissioner is hereby authorized to deduct any necessary fees from Arnold, White & Durkee  
Deposit Account No. 01-2508/INRP:041/HYL.

Respectfully submitted,



Steven L. Highlander  
Reg. No. 37,642

SLH:lew  
Encl.

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**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

*In re* Application of:

GARY L. CLAYMAN

Serial No.: 08/758,033

Filed: November 27, 1996

For: METHOD AND COMPOSITION FOR  
THE DIAGNOSIS AND TREATMENT OF  
CANCER

Group Art Unit: 1632

Examiner: K. Hauda

Atty. Dkt. No.: INRP:041/HYL

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**PETITION TO DIRECT ENTRY OF AMENDMENT  
UNDER 37 C.F.R. §1.127 and §1.181**

**BOX AF**

Assistant Commissioner for Patents  
Washington, D.C. 20231

Dear Sir:

This is a petition to direct entry of an amendment, offered in response to the final Office Action mailed on April 12, 1999, regarding the above-captioned application. The amendment was refused entry, in the Advisory Action mailed on September 20, 1999, on the grounds that the amendment adding the term "catheterization" to claim 109 requires additional search and/or considerations. Applicant respectfully traverses both this statement, and the refusal to enter the amendment.

## REMARKS

### A. Facts

In the response filed on September 8, 1999, applicant offered an amendment to claim 109 as follows:

109. (Twice amended) A method of inhibiting tumor cell growth in a mammalian subject having a solid tumor comprising the step of [continuously] catheterizing and perfusing a tumor site in said patient with a viral expression construct comprising a promoter functional in eukaryotic cells and a polynucleotide encoding a functional p53 polypeptide, wherein said polynucleotide is positioned sense to and under the control of said promoter, the administration resulting in expression of said functional p53 polypeptide in cells of said tumor and inhibition of their growth.

The examiner refused entry of this amendment, in the Advisory Action of September 20, 1999, on the ground that introduction of the term “catheterization” [*sic*, catheterizing] into claim 109 would require “additional search and/or consideration.” However, review of dependent claim 122, which has been pending since November 18, 1997, reveals the following:

122. The method of claim 109, wherein said tumor site is contacted with said expression vector *through a catheter*.

Emphasis added. It is believed, therefore, that introduction of this term into claim 109, in the proposed amendment of September 8, 1999, did not require either additional search or consideration.

**B. Statement of Relief Requested**

Thus, applicant respectfully requests that the Group Director direct entry of the previously filed amendment. However, applicant is filing, concurrent with this petition, an appeal brief and revised amendment that does not contain the term “catheterizing” in claim 109. Should revised amendment be entered, and this petition be subsequently granted, the applicant (now appellant) respectfully requests that the following amendment be made to claim 109:

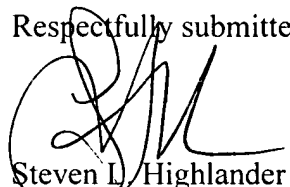
109. (Three times amended) A method of inhibiting tumor cell growth in a mammalian subject having a solid tumor comprising the step of [continuously] catheterizing and perfusing a tumor site in said patient with a viral expression construct comprising a promoter functional in eukaryotic cells and a polynucleotide encoding a functional p53 polypeptide, wherein said polynucleotide is positioned sense to and under the control of said promoter, the administration resulting in expression of said functional p53 polypeptide in cells of said tumor and inhibition of their growth.

Should the Group Director have any questions regarding this petition, a telephone call to the undersigned is respectfully requested.

Date: 11/9/99

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512-418-3000

Respectfully submitted,

  
Steven L. Highlander  
Reg. No. 37,642